

OBJECTIVES: Biologic agents represent significant medical advances for rheumatoid arthritis (RA), and multiple sclerosis (MS). Yet, specialty tiers under the initial coverage limit (ICL) period of Medicare Part D require a coinsurance of up to 33% for such drugs. This study is the first to examine the impact of cost-sharing increases faced with specialty tiers on adherence and discontinuation among Medicare patients using RA and MS biologics. **METHODS:** This quasi-experimental study examined changes in outcomes across the Part D catastrophic coverage period in the previous year (pre-period) and the ICL period in the current year (post-period) for patients not receiving low-income subsidies (non-LIS) who faced coinsurance levels of 5% in the pre-period and 25%-33% in the post-period compared to a control group of LIS patients who faced the same cost-sharing (\$5 copay) in the pre- and post-periods. Using the 2006-2010 5% Medicare files we identified patients with MS (ICD-9-CM 340.xx) and RA (ICD-9-CM 714.xx) with continuous fee-for-service and Part D coverage and use of Part D biologics indicated for MS (N=1887) and RA (N=1982), respectively, during the pre-period. Outcomes included adherence (proportion of days covered ≥ 0.8) and discontinuation (continuous 30-day gap) for Part D-covered, Part B-covered, and all biologics. GEE logit regressions adjusting for patient demographics and clinical severity and Part D plan formulary characteristics were estimated. Patient-level fixed-effects models were used in sensitivity analyses. **RESULTS:** The substantial increase in cost sharing under specialty tiers was associated with lower adherence (MS:OR=0.56, $p < 0.001$; RA:OR=0.50, $p < 0.001$) and higher likelihood of having gaps in Part D biologic (MS:OR=1.56, $p < 0.001$; RA:OR=2.73, $p < 0.001$) among non-LIS compared to LIS patients. Overall biologic use also declined due to limited substitution with Part B biologics in non-LIS patients. Sensitivity analyses showed consistent findings. **CONCLUSIONS:** The increased cost sharing under specialty tiers was associated with a decline in adherence and increase in discontinuation of MS and RA biologics.

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ASSESSING THE GENEROSITY OF DRUG COVERAGE IN THE HEALTH INSURANCE EXCHANGES

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OBJECTIVES: A key portion of the Affordable Care Act's new coverage, particularly for chronic disease, is the prescription drug benefit. Each plan's generosity will depend on the particular mix of drugs for a given patient, not just the benefit structure. For a market basket of drugs, we assess the generosity of drug coverage for the four metal tiers in the Federally Facilitated health insurance exchanges. **METHODS:** We examined the 27 federally facilitated exchanges and 7 partnership exchanges, for which characteristics of all plans on the exchanges were publicly available from data.gov for 2014. These files, however, do not contain drug formulary data, so we also use a unique data source of drug formulary data, from Managed Markets Insight & Technology. We were able to identify a total of 2,826 unique plan-formulary combinations with formulary and price data for 21 drugs in these therapeutic areas. For each drug, we collected the price for a standard prescription fill from drugs.com, which allowed us to convert coinsurance rates into prices. We then created a generosity index as the ratio of the out-of-pocket payment to the price of the drug. **RESULTS:** For individuals with higher out-of-pocket spending, there is considerable variation in the generosity of prescription drug coverage in all metal tiers. Comparisons by plan type indicate that PPO plans provide more generous prescription drug coverage, except in the bronze tier, for which HMO plans are significantly more generous than PPO plans until individuals have spent \$5,000, or more, out of pocket. **CONCLUSIONS:** Given the substantial variation in generosity of drug coverage, consumers may have trouble finding the plan that best balances their ability to pay premiums, tolerance for financial risk, and preferences between prescription drug and all other costs.

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THE UPTAKE OF BIOSIMILAR PRODUCTS BY BRITISH FORMULARIES

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OBJECTIVES: A "biosimilar" is a biological medicine similar to a licensed biological medicine ("originator"). As of October 2014, six biosimilars are licensed and marketed in Great Britain (GB) (three biosimilar filgrastims, two biosimilar epoetins and one biosimilar somatropin). Biological medicines are highly costly to the NHS, so it is expected that biosimilars will have an increasing presence as a cost-saving mechanism. This study explored the uptake of biosimilars within GB formularies. **METHODS:** Websites of acute trusts in England and health boards in Scotland and Wales were searched for the most recent drug formularies. The presence of biosimilars in a formulary was examined for all six products. Formularies that listed at least one biosimilar were considered to have a positive recognition of these products. **RESULTS:** Of 158 acute trusts in England and 21 health boards in Scotland and Wales, 176 websites were available, providing 144 formularies (England: 127, Scotland: 9; Wales: 7; England/Scotland shared: 1). 17 formularies were shared across trusts and boards. At least one biosimilar was listed in 63 formularies. While 45 formularies listed at least one biosimilar filgrastim, 31 and 17 formularies listed biosimilar somatropin and epoetin, respectively. Five formularies listed at least one biosimilar from each of the three classes, 20 formularies listed at least one from two classes, and 38 formularies listed at least one from only one class. In 19 formularies, at least one biosimilar was listed in preference to an originator product as first line therapy (filgrastim: 16; somatropin: 5; epoetin: 1). **CONCLUSIONS:** The results of this survey suggest that 44% of formularies in Great Britain list at least one biosimilar, and in 30% of these, these are listed in preference to the originator product. This appears to be a low level of penetration into formularies given that these biosimilars have been available for over five years.

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IMPACT OF COST SHARING ON SPECIALTY DRUG UTILIZATION AND OUTCOMES: A REVIEW OF THE EVIDENCE AND FUTURE DIRECTIONS

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OBJECTIVES: Payers in the U.S. are increasingly employing aggressive cost sharing strategies for specialty drugs. We conducted a systematic review of the published evidence on the associations between patient cost sharing and use of specialty drugs, use of non-drug medical services, and health outcomes and spending. **METHODS:** A MEDLINE search for U.S.-based studies published in English between 1995 and 2013 was conducted using various combinations of terms for cost sharing and specialty drugs and/or common conditions for which they are indicated. Additional studies were obtained from reference lists of identified studies. Key methodological elements of the included studies were extracted and findings were captured to determine effects of cost sharing. **RESULTS:** We identified 15 articles that focused on one or more diseases, including Multiple Sclerosis (n=8), cancer (n=7), Rheumatoid Arthritis (n=5), and other conditions (n=4). Majority of the studies (n=14) used administrative claims data on privately insured patients from the year 2009 or earlier, during which time few private insurers were employing aggressive cost sharing for specialty drugs. Outcomes included prescription abandonment (n=2), initiation or any utilization (n=7), adherence (n=8), persistence/discontinuation (n=6), number of claims (n=1), and drug spending (n=1). Findings generally indicated reductions in specialty drug utilization associated with higher cost sharing. However, the evidence was not consistent; the magnitude and/or statistical significance of the effects of cost sharing varied by disease and type of outcome. None of the studies examined the effect of specialty tier cost sharing seen under Medicare Part D or health insurance exchanges; or the effect of cost sharing on medical utilization, spending, or health outcomes. **CONCLUSIONS:** Evidence till date generally indicates reductions in specialty drug utilization associated with higher cost sharing, with effects varying by type of disease and specialty drug outcome. We draw upon our findings and the gaps in evidence to summarize future directions for research and policy.

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WHEN IS HEALTH ECONOMICS AND OUTCOMES RESEARCH EVIDENCE IMPORTANT TO U.S. PAYERS?

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OBJECTIVES: The impact of health economics and outcomes research (HEOR) evidence on reimbursement decisions in the U.S. is not well understood, yet the continued and increasing investment in HEOR by pharmaceutical companies indicates a perceived positive impact. We sought to understand U.S. payers' preferences for HEOR evidence when making reimbursement decisions and to assess the alignment between payers and pharmaceutical companies with respect to the types of HEOR evidence that are important for various product and market scenarios. **METHODS:** We conducted an online, stated choice survey with individuals involved in the formulary decision-making process for U.S. payer and pharmacy benefit manager (PBM) organizations and those involved in the decision to invest in HEOR for pharmaceutical companies. We presented each individual with thirteen product profiles and asked them to rate the importance of several types of HEOR evidence to support U.S. formulary placement decisions for each profile. We used a logistic regression model to assess the product and market attributes that are associated with the stated importance of each type of evidence and to compare the alignment between respondents from pharmaceutical and payer/PBM organizations. **RESULTS:** We received 31 responses from payers and 63 responses from individuals within pharmaceutical companies. Preliminary results indicate differences between the two stakeholder groups in the perceived importance of budget impact, resource utilization/cost offset, and adherence/compliance evidence. We report the most influential factors in the types of HEOR evidence that are stated to have an impact on formulary decision-making. **CONCLUSIONS:** The findings of this survey provide us with a better understanding of the specific types of HEOR evidence payers are interested in for pharmaceutical products entering the market. This nuanced understanding of payer preferences may allow for greater alignment between payer organizations and pharmaceutical companies, and will assist pharmaceutical companies in planning future investments.

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THE CALIFORNIAN TECHNOLOGY ASSESSMENT FORUM æ" THE ARRIVAL OF COST-UTILITY APPRAISALS OF DRUGS IN THE USA?

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OBJECTIVES: The Californian Technology Assessment Forum (CTAF) publishes reports that make recommendations on the comparative clinical effectiveness and value of medical interventions. The recommendations of CTAF, which is managed by the Institute for Clinical and Economic Review and funded by Blue Shield of California, are not binding and they do not determine health plan benefit coverage. In April 2014, CTAF gained a degree of public attention when they recommended that the Hepatitis C virus (HCV) treatments OLYSIO and SOVALDI be only used immediately in patients with advanced liver disease or those awaiting transplants based on a report including cost-utility economic modelling. This research aimed to systematically analyse all CTAF reports to determine what types of health technologies they assess, how restrictive their recommendations are, and how this has evolved over time. **METHODS:** All publically available CTAF reports were extracted and their date, indication, technology type, and recommendation were extracted. **RESULTS:** CTAF have issued 119 medical technologies appraisals since October 2002. 26/119 (22%) were recommended, 18/119 (15%) received restricted recommendations, and 75/119 (63%) not recommended. 33/119 appraisals (28%) were for diagnostic tests, 28/119 devices (24%), 27/119 (23%) surgery, 25/117 (21%) radio/radiation/laser-based emission therapies, 3/117 (3%) other, and only 3/117 (3%) branded drugs. The branded drug submissions were for Avastin in metastatic